REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the remarks that follow.

Claims 1, 7-10 and 21-25 are pending and are being represented for consideration. Claims 2-6 and 11-20 were previously cancelled. Applicant has amended claims 1 and 24 to address the section 112-second paragraph rejections. Support for the amendments to claim 1 are found throughout the specification and specifically on page 4, lines 2-8 and on pages 31 and 32 of published PCT application No. WO/ 2005/069900. These amendments are further discussed below.

Information Disclosure Statement (IDS)

Applicants have filed an IDS providing dates for the references lined-through by the Office in the IDS filed October 25, 2006 (see Office Action, page 2, lines 8-12). Applicants request that the Office duly initial these citations in the current IDS to indicate consideration.

Rejection for Indefiniteness

The PTO puts forth several issues under the rubric of "indefiniteness." Applicants address each of these in the same order as presented in the Office action.

Issue 6:

The PTO states that the phrase "detectably labeled substituted 2-azetidinone glucuronide compound selected from the group consisting of compound 1, compound 2, compound 8 and...." renders claim 1 indefinite. Specifically, it is the PTO's contention that the objected phrase parlays reliance on extraneous information to practice the inventive method, and therefore, the metes and bounds of the claimed invention are undefined. See paragraph bridging pages 2 and 3.

Although, Applicants do not acquiesce to the propriety of the rejection, Applicants have amended claim 1 to recite the structures of the underlined compounds. Thus, the indefiniteness rejection is most and should be withdrawn.

Issues 7 - 10:

In item 7, the PTO states that claim 1 is indefinite because it recites both a broad genus (Formula IIa compounds), together with the recitation of a narrower species, compound 2, that falls within the recited genus. See Office action at page 3.

Without acquiescing to the propriety of this rejection, Applicants have chosen to advance prosecution by deleting compound 2 to address the PTO's concern. Accordingly this rejection is moot.

On page 4, item 8, the PTO has rejected claim 1 for indefiniteness alleged in relation to the use of two alternative definitions for selecting the identity of substituent groups shown in Formula IIa. Without acquiescing to the examiner's stated rationale, applicants have amended claim 1 to delete <u>one recitation</u> of substituent group identities. Thus, the rejection is moot.

In item 9, the PTO alleges that the specification does not disclose recited compound 8. Contrary to the PTO's comments on point, however, the specification teaches that "[C]ompound 8 is an analog of compound 2 wherein the hydroxyl group in the 3-hydroxyl propyl moiety of 2 is replace with an oxo group." See PCT publication at page 94, lines 14-15.

Based on this teaching and the disclosed structure of compound **2** (*see*, page 83 and pending claim 22), a person of ordinary skill in the chemical art would have readily understood compound **8** to contain a =O (oxo) group in place of the –OH group at the C-3 position of the propyl moiety. Stated differently, compound **8** has a keto group in place of a hydroxy group at position C-3 of the propyl moiety. See below. Thus, compound **8** is disclosed in the specification as filed.

$$\begin{array}{c} OH \\ OH \\ OO_2H \\ OO_2H \\ OO_3H \\ OO_4 \\ OO_5 \\ OO_7 \\ OO_8 \\ OO_$$

The PTO states in issue 10 that dependent claim 24 is indefinite because "compound 7 does not read on the compounds of claim 1." Applicants have amended claim 24 to address the PTO's concerns. Thus, the rejection is moot.

Issue 11:

The PTO rejects claim 1 for indefiniteness alleged in relation to (a) not reciting the detection of the detectably labeled 2-azetidinone, and (b) for alleged lack of clarity over the term "modulation." See office action at page 4 and 5.

As stated above claim 1 clearly delineates the metes and bounds of the inventive method. Claim 1 is modified to recite the steps of measuring the amount of detectable label bound to NPC1L1, which measurement is used to identify if the candidate compound is an NPC1L1 ligand. Thus, the rejection in point (a), above is moot.

Moreover, the amendments to claim 1 also address the examiner's concern regarding the lack of clarity rejection over the term "modulation." Thus, this rejections is also moot.

On page 5 of the Office action, the examiner contends that none of the prior art identified as being pertinent teach or suggest the use of a "glucuronidated ezetimibe" as a target for NPC1L1. Accordingly, in the absence of such a disclosure in the prior art, the PTO is heard to state that the claimed method is novel and non-obvious.

CONCLUSION

Having advanced credible remarks to obviate the section 112-second paragraph issues and in support of patentability of the claimed invention, Applicant believes that the present application is now in condition for allowance and requests an early indication to this effect.

Atty. Dkt. No. 059893-0121

The Examiner is invited to contact the undersigned if any issues that warrant further discussion remain.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16 1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, then the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 14-Sep-2010

By /Rouget F. Henschel/

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